

27 February 2025

Call for submissions – Proposal P1064

Australian only Infant Formula Product Standard

Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared to make minor amendments to the Australia New Zealand Food Standards Code which reflect the New Zealand Government's decision to opt out of the revised Standard 2.9.1, and has prepared a draft food regulatory measure. Pursuant to section 68 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for comment from appropriate government agencies to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

For information on how FSANZ manages personal information when you make a submission, see FSANZ's [Privacy Policy](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically by emailing your submission directly to nutrition@foodstandards.gov.au.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 27 March 2025

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making a submission to this proposal can be sent to nutrition@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

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Executive summary

Food Standards Australia New Zealand (FSANZ) prepared Proposal P1064 to amend the Australia New Zealand Food Standards Code (the Code) to reflect that, following Proposal P1028, Standard 2.9.1 of the Code does not apply in New Zealand.

The regulatory changes introduced by Proposal P1028 were endorsed by the Food Ministers' Meeting (FMM09) on 25 July 2024 and gazetted on 13 September 2024. These changes, among other things, amended Standard 2.9.1, the Code's infant formula standard.

On 5 August 2024, the New Zealand Government formally notified the Food Ministers' Meeting in accordance with paragraph 14 of Annex D of *The Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* that New Zealand would opt out of the amended infant formula product standard developed under P1028.

As a result, Standard 2.9.1 of the Code now applies in Australia only.

The purpose of this proposal is to amend Standards 1.1.1 and 2.9.1 of the Code by inserting Notes that state Standard 2.9.1 applies in Australia only. These Notes will have no legal effect but inform readers of the existing legal situation.

FSANZ assessed Proposal P1064 and has prepared a draft variation. FSANZ invites submissions on the draft variation from the notified government agencies.

1 Introduction

1.1 The proposal

Food Standards Australia New Zealand (FSANZ) prepared Proposal P1064 to amend Standards 1.1.1 and 2.9.1 of the Code by inserting Notes that state Standard 2.9.1 – the infant formula products standard - applies in Australia only. These Notes will reflect the New Zealand Government's decision to opt out of the amended infant formula product standard developed under Proposal P1028.

The regulatory changes were approved by the FSANZ Board on 4 June 2024, endorsed by the Food Ministers' Meeting (FMM09) on 25 July 2024 and gazetted on 13 September 2024.

On 5 August 2024, the New Zealand Government formally notified the Food Ministers' Meeting in accordance with paragraph 14 of Annex D of *The Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* (the Treaty)¹ that New Zealand would opt out of the amended infant formula product standard.

As a result, Standard 2.9.1 now applies only in Australia.

Paragraph 16 of Annex D of the Treaty provides that where New Zealand has opted out of a food standard, the food standard in the Code must be annotated to indicate that the standard does not apply in New Zealand. These annotations also ensure that those who use and rely on the Code are aware of its legal application.

For these reasons, FSANZ was required to prepare Proposal P1064.

1.2 The current standards

As noted above, and for the reasons explained below, the relevant standards are:

- Standard 1.1.1 – Structure of the Code and general provisions
- Standard 2.9.1 – Infant formula products

1.3 Reasons for preparing the Proposal

The New Zealand Government opted out of the amended infant formula products standard (as per Proposal P1028) under Annex D of the Treaty².

As a result, Standard 2.9.1 of the Code does not apply in New Zealand.

The Treaty now requires FSANZ to make editorial amendments to Standard 2.9.1 and to Standard 1.1.1 to reflect that fact.

1.4 Procedure for assessment

The proposal is being assessed under the Minor Procedure as set out in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)

The Minor Procedure is used for Proposals involving amendments to the Code that, if made, would not directly or indirectly:

- (a) impose, vary or remove an obligation on any person; or
- (b) create, vary or remove a right of any person; or
- (c) otherwise alter the legal effect of the measure.

¹ www.foodregulation.gov.au/resources/publications/new-zealand-notice-opt-out-proposal-p1028-infant-formula-standard

² www.foodregulation.gov.au/resources/publications/agreement-australia-new-zealand-joint-food-standards-system

For the reasons explained above, the proposed amendments in this case meet these criteria. The Minor Procedure requires one statutory round of consultation with ‘appropriate government agencies’ only.

The Act defines ‘appropriate government agencies’ to mean:

- each Commonwealth, State, Territory and New Zealand Department administered by a Minister who is a member of Food Ministers’ Meeting (FMM)
- any other body that has an officer on the Food Regulation Standing Committee
- any other Commonwealth, State, Territory and New Zealand body or officer that the FSANZ Board (or delegate) considers has a particular interest in the matter.

2 Summary of the assessment

2.1 Risk assessment

No public health and safety concerns have been identified in relation to this proposal or the draft variation that has been prepared. As explained below, the draft variation will make editorial amendments to the Code that do not and cannot alter the legal effect of the Code.

The reasons for each of the proposed amendments to be made by the draft variation are set out below.

Proposed amendment to subsection 1.1.1—2(2)

Subsection 1.1.1—2(2) of the Code sets out the structure of the Code and lists each standard. It provides, in effect, a table of contents for the Code. The list of standards in that section identifies for readers which Standards of the Code apply in Australia only by the use of a Note after the entry for each relevant Chapter or standard.

The proposed amendment to subsection 1.1.1—2(2) would insert a Note stating ‘Applies in Australia only’ after the reference to Standard 2.9.1. The Note would inform readers of the fact that Standard 2.9.1 of the Code applies in Australia only.

Proposed amendment to subsection 1.1.1—3, Note 1

Section 1.1.1—3 sets out to what food the Code applies. Subsection 1.1.1—3(1) provides that, unless stated otherwise, the Code applies to food that is sold, processed or handled for sale or imported into Australia or New Zealand. Note 1 to that subsection lists those standards or provisions in the Code which the New Zealand Government has not incorporated or adopted under the *Food Act 2014* (NZ).

Proposed amendment to Note 1 of subsection 1.1.1—3 would add a reference to ‘Standard 2.9.1 (infant formula products)’ to the abovementioned list in that Note.

The reference would inform readers of the fact that Standard 2.9.1 of the Code applies in Australia only and has not been incorporated or adopted under the *Food Act 2014* (NZ).

Proposed amendment to Standard 2.9.1 (under the title of the standard)

The Code also identifies Standards that do not apply in New Zealand by use of a Note under the title of the relevant Standard and that states the Standard applies in Australia only.

At present, the following Note is included under the title of Standard 2.9.1 – ‘**Note 2** The provisions of the Code that apply in New Zealand are incorporated in, or adopted under,

the *Food Act 2014* (NZ). See also section 1.1.1—3’.

This Note is incorrect as Standard 2.9.1 of the Code has not been incorporated in or adopted under the *Food Act 2014* (NZ) and does not apply in New Zealand.

The proposed amendment to Standard 2.9.1 will amend the text of Note 2 to state that the Standard applies in Australia only and that New Zealand has under Annex D of the *Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* opted out of the Standard.

The above is the same approach as taken for other Standards of the Code that do not apply in New Zealand, such as Standard 1.4.2 – Agvet chemicals and Standard 1.6.2 – Processing requirements for meat.

2.2 Risk management

FSANZ’s assessment is that amendment of the Code in the manner proposed is the appropriate risk management response. The proposed amendments are editorial and machinery in nature and merely reflect the existing law.

The proposed amendments do not have any legal effect in and of themselves. Nor do they amend any provisions of Standard 2.9.1 of the Code. The Code requirements remain unchanged. As such no potential public health and safety concerns have been identified.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ’s standards development process. As this proposal is being assessed under the Minor Procedure, consultation on the proposed draft variations is being undertaken with notified government agencies as required by the Act.

2.4.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia is obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

The proposed amendments will not change the legal effect of the Code. They will merely reflect what is the existing law in terms of the Code’s application and inform readers of that fact. Proposal P1064 is unlikely to have a significant effect on international trade as it will not impose any new regulatory requirements for Australia. Therefore, a notification to the WTO under Australia’s obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.5 FSANZ Act assessment requirements

When assessing this proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

2.5.1 Section 59

2.5.1.1 Consideration of costs and benefits

FSANZ is required to assess if the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the proposal outweigh the costs to the community, government or industry that would arise from the development or variation of the food regulatory measure.

Proposal P1064 will not change the law or impose any new requirements. Its purpose is to reflect the existing law, which is that Standard 2.9.1 of the Code does not apply in New Zealand. None of the proposed amendments will have any legal effect in or of themselves, or impose any obligations on or vary the rights of any person. As such, the draft variation is not expected to impose costs on the community, industry or government that are additional to those already generated by compliance with or enforcement of the existing Code.

Not proceeding with Proposal P1064 and the proposed draft variation may result in regulatory uncertainty (e.g. stakeholder misunderstandings). This is because, without the proposed draft variation, the Code will not reflect existing law.

For this reason, one can reasonably conclude that the benefits to the community, government or industry that will arise from the draft variation will outweigh any costs (if they exist).

2.5.1.2 Other measures

For the reasons explained above, there are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the proposal.

2.5.1.3 Any relevant New Zealand standards

FSANZ understands that:

- Standard 2.9.1 as it was in force immediately prior to the gazettal of the variations made by Proposal P1028 remains in force in New Zealand as a part of New Zealand law. That is, as it had previously been adopted under the *New Zealand Food Act* and no action has been taken by the New Zealand Government to amend or revoke it under section 400 of the *New Zealand Food Act*.
- Standard 2.9.1 as it is in force in New Zealand is not part of the Code for the purposes of the FSANZ Act. Nor is it covered by the 'Australian New Zealand Food Standards System' established by the Treaty.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

FSANZ had regard to the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this proposal:

- the protection of public health and safety
- the provision of adequate information relating to food to enable consumers to make informed choices
- the prevention of misleading or deceptive conduct.

FSANZ concluded that the proposed variations, if approved, will have little or no direct impact in terms of these objectives. As mentioned above, no potential public health and safety concerns have been identified.

The purpose of Proposal P1064 is to reflect the existing law as it relates to the application of Standard 2.9.1 of the Code in New Zealand, and for the Australian Government to meet its obligations under the Treaty. The amendments required are editorial and machinery in nature and do not have any legal effect, consequently, the draft variation does not raise public health and safety issues for consideration.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence
- the desirability of an efficient and internationally competitive food industry
- the promotion of fair trading in food
- any written policy guidelines formulated by the FMM.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Attachments

- A. Draft variation to the Australia New Zealand Food Standards Code
- B. Draft Explanatory Statement

Attachment A – Draft variation to the Australia New Zealand Food Standards Code



Food Standards (Proposal P1064 – Australian only Infant Formula Product Standard) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's name and position title]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1064 – Australian only Infant Formula Product Standard) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Standard 1.1.1 – Structure of the Code and general provisions

[1] Subsection 1.1.1—2(2)

Omit:

Standard 2.9.1 Infant formula products

Substitute:

Standard 2.9.1 Infant formula products

Note Applies in Australia only

[2] Note 1 to Subsection 1.1.1—3(1)

Omit:

(vii) Chapter 3 (food safety standards) and Chapter 4 (primary production and processing standards).

Substitute:

(vii) Standard 2.9.1 (infant formula products);

(viii) Chapter 3 (food safety standards);

(vix) Chapter 4 (primary production and processing standards)

Standard 2.9.1 – Infant Formula Products

[3] Note 2 to the title of the Standard

Repeal the Note, substitute:

Note 2 This Standard applies in Australia only. New Zealand has under Annex D of the *Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* opted out of this Standard. See also section 1.1.1—3.

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Proposal P1064 – Australian only Infant Formula Product Standard) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1064 to amend Standards 1.1.1 and 2.9.1 of the Code by inserting Notes in each to advise readers that Standard 2.9.1 applies in Australia only

The Authority considered the proposal in accordance with Division 2 of Part 3 and has prepared a draft variation - the *Food Standards (Proposal P1064 – Australian only Infant Formula Product Standard) Variation* (the draft variation)

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers' Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or

instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared the draft variation to amend Standards 1.1.1 and 2.9.1 of the Code by inserting Notes in each to reflect the fact that Standard 2.9.1 applies in Australia only and to inform readers of the fact. Standard 2.9.1, the Code's infant formula standard, was amended in 2024 as result of Proposal P1028. That Proposal's regulatory changes were endorsed by the FMM on 25 July 2024 and gazetted on 13 September 2024. On 5 August 2024, the New Zealand Government formally notified the FMM in accordance with paragraph 14 of Annex D of *The Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* that New Zealand would opt out of the amended infant formula standard developed under P1028. As a result, Standard 2.9.1 of the Code now applies in Australia only.

4. Documents incorporated by reference

The proposed draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1064 will include one round of consultation with government agencies notified in accordance with the FSANZ Act. This follows an assessment and the preparation of a draft variation and associated assessment summary.

A regulation impact statement (RIS) has not been prepared for this proposal. Under changes to impact analysis requirements, the Authority is not required to seek confirmation from the Office of Impact Analysis (OIA) that a RIS is not required. This is because the amendments proposed in the draft variation are considered unlikely to have more than a minor regulatory impact. This is in line with previous advice from the OIA on similar proposals (for example Proposal P1061 – Code Maintenance Proposal 2023, OIA reference 22-03854).

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the Legislation Act 2003.

7. Variation

Clause 1 of the draft variation provides that the name of the variation is the *Food Standards (P1064 – Australian only Infant Formula Product Standard) Variation*.

Clause 2 of the draft variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the draft variation provides that the variation will commence on the date of gazettal of the instrument.

Item [1] of the Schedule would amend Subsection 1.1.1—2(2) of the Code.

Subsection 1.1.1—2(2) of the Code sets out the structure of the Code and lists each standard. It provides, in effect, a table of contents for the Code. The list of standards in that subsection identifies for readers which Standards of the Code apply in Australia only by the

use of a Note after the entry for each relevant Chapter or standard.

The proposed amendment to subsection 1.1.1—2(2) would insert a Note stating ‘Applies in Australia only’ after the reference to Standard 2.9.1. The Note would inform readers of the fact that Standard 2.9.1 of the Code applies in Australia only.

Item [2] of the Schedule would amend Note 1 to subsection 1.1.1—3(1).

Section 1.1.1—3 sets out to what food the Code applies. Subsection 1.1.1—3(1) provides that, unless stated otherwise, the Code applies to food that is sold, processed or handled for sale or imported into Australia or New Zealand. Note 1 to that subsection lists those standards or provisions in the Code which the New Zealand Government has not incorporated or adopted under the Food Act 2014 (NZ).

Proposed amendment to Note 1 of subsection 1.1.1—3 would amend the above-mentioned list in the Note by replacing the existing paragraph (vii) – which refers to “Chapter 3 (food safety standards) and Chapter 4 (primary production and processing standards)” - with three new paragraphs as follows:

- (vii) Standard 2.9.1 (infant formula products);
- (viii) Chapter 3 (food safety standards);
- (vix) Chapter 4 (primary production and processing standards)

The effect of this Item would be to add Standard 2.9.1 to the Note’s list of Code provisions that have not been incorporated or adopted under the *Food Act 2014 (NZ)*. It would also separate the references to Chapter 3 (food safety standards) and Chapter 4 (primary production and processing standards), currently combined in one paragraph (vii), into their own paragraphs: (viii) and (vix).

The proposed amendment would inform readers of the fact that Standard 2.9.1 of the Code applies in Australia only.

Item [3] of the Schedule would repeal and replace Note 2 to the title of Standard 2.9.1.

The Code identifies Standards that do not apply in New Zealand by use of a Note under the title of the relevant Standard and that states the Standard applies in Australia only.

At present, the following Note is included under the title of Standard 2.9.1

Note 2 The provisions of the Code that apply in New Zealand are incorporated in, or adopted under, the *Food Act 2014 (NZ)*. See also section 1.1.1—3.

This Note is incorrect as Standard 2.9.1 of the Code has not been incorporated in or adopted under the New Zealand Food Act and does not apply in New Zealand.

The proposed amendment to Standard 2.9.1 will amend the text of Note 2 to state as follows

Note 2 This Standard applies in Australia only. New Zealand has under Annex D of the *Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* opted out of this Standard. See also section 1.1.1—3.

The proposed amendment would inform readers of the fact that Standard 2.9.1 of the Code applies in Australia only. The above is the same approach as taken for other Standards of the Code that do not apply in New Zealand, such as Standard 1.4.2 – Agvet chemicals and Standard 1.6.2 – Processing requirements for meat.